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| 09/916,440 | 07/30/2001 | Jing Wu | 002010-586 | 2003 |

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EXAMINER

KIFLE, BRUCK

ART UNIT PAPER NUMBER

1624


DATE MAILED: 04/05/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|---------------------------------------|----------------------------------|
| Application No. 09/916,440 | Applicant(s) Wu et al. |
| Examiner Bruck Kifle, Ph.D. | Art Unit 1624 |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Mar 18, 2002
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 91-145 is/are pending in the application.
- 4a) Of the above, claim(s) 96-103, 105-108, 123-130, and 132-135 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 91-95, 104, 109-122, 131, and 136-145 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some* c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

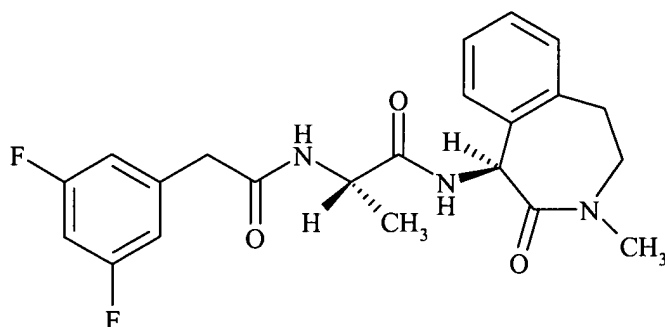
Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 and 4 20) Other:

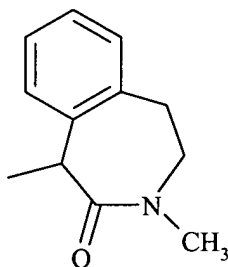
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Election/Restriction

Applicant's election without traverse of the compound depicted below in Paper No. 6 is acknowledged.



The search was conducted to embrace compounds wherein W, together with -C(H)_pC(=X), and Q form the ring system:



Claims 96-103, 105-108, 123-130 and 132-135 along with subject matter not embraced by this ring system of the remaining claims are withdrawn from consideration as being drawn to non-elected subject matter.

Improper Markush Rejection

Claims 91-95, 104, 109-122, 131 and 136-145 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The ring formed by W, together with -C(H)_pC(=X), and Q are defined in such a way

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that they keep changing the core of the compound that determines the classification. By changing these values, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula IA and IB do not have a significant structural feature that is shared by all of its alternatives which is inventive. The structural formula IA and IB only have the -C(O)-NH-CH(R²)-C(O)-NH- fragment as common. Compounds embraced by formula IA and IB are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

Limiting the claims to compounds wherein W, together with -C(H)_pC(=X), and Q form the elected ring system (the benzoazepinone ring) would overcome this rejection.

Claim Rejections - 35 USC § 112

Claims 91-95, 104, 109-122, 131 and 136-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) In the independent claims the terms substituted alkyl, substituted alkenyl, substituted alkynyl, substituted cycloalkenyl are present. The term "substituted" without saying which substituents

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are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not.

ii) The term "cycloalkyl" is indefinite because it is not known how many atoms make up the ring and what kind of a ring is intended (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.).

iii) The term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.

iv) The term "heterocyclic" is indefinite because it is not known how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended.

v) The independent claims end with the phrase "and pharmaceutically acceptable salts thereof." This is improper Markush language because it is not in the alternative form. The term "or" is suggested in place of "and".

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the independent claims recite the broad recitations “optionally substituted heteroaryl” and “substituted alkyl”, and the claims also recite “2-aminopyrid-6-yl” and “-(CH₂)₄NHC(O)OC(CH₃)₃” which is the narrower statement of the range/limitation.

Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

Claim 145 has 68 pages of compounds. This number of compounds cannot be considered “a reasonable number” according to rule 1.140(a). See also MPEP rule 1.141(a) reproduced below.

§ 1.141 Different inventions in one national application.

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (1.75) or otherwise include all the limitations of the generic claim.

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Provisos

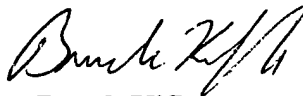
There are provisos in the claims that exclude compounds embraced by the claims. If these provisos are present to avoid prior art, applicants are urgently requested to point out these references to the examiner because of their importance in the examination of the claims.

The search revealed that the elected compound is disclosed in several of Applicants pending applications. See for example WO 9/67221 and WO 98/28268. Also, WO 2001/034571 overlaps generically. Applicants are required to maintain a clear line of demarcation between the applications. See MPEP § 822.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

April 4, 2002


Bruck Kifle
Primary Examiner
Art Unit 1624